

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P.,)	
PURDUE PHARMACEUTICALS L.P.,)	
and RHODES TECHNOLOGIES,)	C.A. No. 15-cv-13099-FDS
)	(lead case)
Plaintiffs,)	
v.)	C.A. No. 17-cv-11814-FDS
)	(member case)
COLLEGIUM PHARMACEUTICAL, INC.,)	C.A. No. 21-cv-10598-FDS
)	(member case)
Defendant)	

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT FOR THE '961 AND '434 PATENTS

I. Identification of Agreed or Disputed Terms and Proposed Constructions

The following tables set forth the list of disputed and agreed-upon claim terms and phrases in asserted patents U.S. Patent Nos. 9,693,961 (“’961 patent”) and 10,407,434 (“’434 patent”), and the parties’ respective proposed constructions.

Table 1.a.
Disputed Terms and Phrases for '961 Patent

	Disputed Claim Term or Phrase	Patent/Claims	Plaintiffs' Proposed Construction	Collegium's Proposed Construction
1.	abuse deterrent dosage form	'961 patent claims 1 and 16	dosage form including a means of causing a reduced potential for abuse	“dosage form that is subject to less parenteral, intranasal, or oral abuse than other dosage forms,” or, to preserve validity, “dosage form that implements the use of an aversive agent to deter abuse”
2.	homogenous mixture	'961 patent claims 1, 11, and	a single-phase mixture having uniform	a mixture where the ingredients are

	Disputed Claim Term or Phrase	Patent/Claims	Plaintiffs' Proposed Construction	Collegium's Proposed Construction
		16	composition and properties throughout	uniformly distributed and need not form a single phase

Table 1.b.
Disputed Terms and Phrases for '434 Patent

	Disputed Claim Term or Phrase	Patent/Claims	Plaintiffs' Proposed Construction	Collegium's Proposed Construction
1.	dissolving the resultant oxycodone free base or oxycodone HCl from step (i) in a suitable recrystallization solvent	'434 patent claim 1	plain and ordinary meaning (i.e., creating a solution of the oxycodone free base or oxycodone HCl from step (i) with a solvent that is capable of recrystallization.)	creating a solution of the resultant oxycodone free base or oxycodone HCl from step (i) for recrystallization at or above 70 degrees Celsius using a solvent where oxycodone HCl or oxycodone free base is reasonably soluble at temperatures above room temperature and insoluble or nearly insoluble at temperatures at or below room temperature, and where the impurity is soluble at or below room temperature or insoluble at all temperatures
2.	cooling the recrystallization solvent to precipitate	'434 patent claim 1	lowering the temperature to cause purified oxycodone free base or oxycodone HCl to come out of solution	lowering the temperature to cause purified oxycodone free base or oxycodone HCl to come out of solution in

				crystalline form
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Table 2
Agreed-Upon Terms and Phrases

	Claim Term or Phrase	Patent/Claims	Agreed-Upon Construction
1.	Preamble of claim 1 (A process of purifying oxycodone free base or oxycodone HCl that contains 8 α , 14-dihydroxy-7,8-dihydrocodeinone or HCl salt thereof in the oxycodone free base or oxycodone HCl)	'434 patent claim 1	The preamble is a limitation of the claim and has its plain and ordinary meaning.
2.	reducing	'434 patent claim 1	plain and ordinary meaning (i.e., lowering the amount of 8 α ,14-dihydroxy-7,8-dihydrocodeinone or HCl salt thereof in the oxycodone free base or oxycodone HCl to less than it was prior to step (i))

II. Ranking of Order of Importance of Terms and Phrases to Be Construed

The parties were able to reach agreement on the ranking of the order of importance of the terms and phrases to be construed, as set forth in Tables 1.a. and 1.b. above.

III. Claim Construction Hearing

The parties anticipate that two hours will be sufficient for the claim construction hearing,

to be split evenly between the parties (i.e., one hour per side). Unless otherwise directed by the Court, the parties propose to present their arguments on a term-by-term basis in the order set forth in Table 1 above. Plaintiffs will present first with respect to each of the '961 patent terms, followed by Collegium. Collegium will present first with respect to each of the '434 patent terms, followed by Plaintiffs. The parties do not intend to call live witnesses at the hearing.

Unless requested by the Court, the parties do not plan to present a formal tutorial on the relevant technology; however, either party may present a brief background prior to presenting their respective arguments on the first term. The parties will send a PDF version of their PowerPoint slides, if any, to the Court by 12:00pm ET one day before the hearing (i.e., Monday, October 4).

Attached as Appendix A is the parties' joint claim construction chart, noting each party's proposed construction of each term, and supporting evidence.

Respectfully submitted

Date: September 10, 2021

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the NEF and paper copies will be sent to those indicated as non-registered participants on September 10, 2021.

/s/ Christopher M. Morrison
Christopher M. Morrison

APPENDIX A TO JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
	'961 Patent				
1.	abuse deterrent dosage form	dosage form including a means of causing a reduced potential for abuse	<p>'961 patent at 1:1-2, 1:27-41, 4:27-29, 3:11-15, 5:33-36, 6:52-57, 6:64-7:14, 15:28-23:51, 15:62-16:31, 17:42-43, 17:43-46, 17:64-18:7, 19:41-44, 19:54-55, 28:35-41.</p> <p>'961 patent at claims 1, 4-6, 8-10, 12-14, and 16; <i>id.</i> at 2:44-51, 8:14-19, 15:28-23:53, 6:64-7:12, 28:36-41, 2:48-51, 3:31-32, 33:8-46, 33:42-45, 2:63-64, 3:15-16, 3:4, 6:27-30, 6:52-57, 2:44-47, 2:28-51, 2:56-61, 2:62-66, 3:3-7, 3:11-15, 3:26-33, and Example 3.</p>	<p>"dosage form that is subject to less parenteral, intranasal, or oral abuse than other dosage forms," or to preserve validity, "dosage form that implements the use of an aversive agent to deter abuse"</p>	<p><i>See, e.g.</i>, '961 patent at 2:31-39, 2:52-61, 2:66-3:2, 3:7-10, 3:15-19, 3:44-54, 4:27-29, 31:14-41:35, <i>see also id.</i> at claims 1-17.</p> <p><i>See, e.g.</i>, D.I. 188, Exs. B-G; Constantinides Dep. at 46:14-21, 47:16-19, 65:18-20, 72:17-23, 78:23-80:8, 80:22-81:5, 82:13-23, 82:24-83:3, 83:17-22, 91:17-92:4, 92:22-93:4, 99:25-100:5</p>

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
			<p><i>See, e.g.,</i> Constantinides Dep. Tr. at 43:7-21, 43:22-44:11, 45:16-46:7, 97:2-99:13.</p> <p>Exhibits 1-20 to Plaintiffs' Preliminary Brief re '961 patent (D.I. 187-1 to D.I. 187-20).</p> <p>Exhibits 21-26 to Plaintiffs' Responsive Brief re '961 patent (D.I. 195-2 to D.I. 195-7).</p> <p>Constantinides Declarations in support of Plaintiffs' Preliminary and Responsive Briefs re '961 patent (D.I. 187-21; D.I. 195-1¹).</p>		

¹ In conjunction with its Responsive Claim Construction Brief, Purdue filed a supplemental declaration of its expert Panayiotis

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
2.	homogenous mixture	a single-phase mixture having uniform composition and properties throughout	<p>'961 patent at 1:1-2, 1:27-41, 4:27-29, 3:11-15, 5:33-36, 6:52-57, 6:64-7:14, 15:28-23:51, 15:62-16:31, 17:42-43, 17:43-46, 17:64-18:7, 19:41-44, 19:54-55, 28:35-41.</p> <p>'961 patent at 17:42-52; 17:64-18:25, and Examples 1, 2, 4-6, 9.</p> <p>Exhibits 1-20 to Plaintiffs' Preliminary Brief re '961 patent (D.I. 187-1 to D.I. 187-20).</p> <p>Exhibits 21-26 to Plaintiffs' Responsive Brief re '961 patent (D.I. 195-2 to D.I. 195-7).</p>	a mixture where the ingredients are uniformly distributed and need not form a single phase	<p><i>See, e.g.</i>, '961 patent at 15:30-23:51, 41:1-3, <i>see also id.</i> at Example 16, claims 1-17</p> <p><i>See, e.g.</i>, D.I. 188, Exs. B-G; D.I. 197, Exs. H-I; McConville Decl. ¶¶ 19-32, Exs. 1-4; McConville Dep. at 72:17-73:13, 74:10-23, 260:20-261:24; Constantinides Dep. at 41:24-42:8, 105:2-11, 107:21-25, 108:23-109:4, 109:16-19, 110:14-25, 111:13-17, 112:21-113:5, 114:18-24, 115:20-118:14, 119:23-120:11, 120:23-121:4, 123:20-23, 124:18-125:3, 125:16-19, 146:11-24, 147:22-25, 148:11-15, 155:5-156:16, 157:24-</p>

Constantinides, Ph.D. (D.I. 195-1). On October 16, 2018, Collegium filed a Motion to Strike this supplemental declaration. (D.I. 203). Plaintiffs opposed Collegium's motion. (D.I. 207.)

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
			<p>Constantinides Declarations in support of Plaintiffs' Preliminary and Responsive Briefs re '961 patent (D.I. 187-21; D.I. 195-1).</p> <p><i>See, e.g.,</i> McConville Dep. Tr. at 33:11-34:16, 39:25-40:4, 49:18-50:9, 52:19-53:9, 55:25-56:4, 56:22-57:16, 58:5-11, 62:3-13, 62:3-6, 64:2-5, 64:17-23, 68:5-25, 69:7-16, 72:17-73:13, 74:10-23, 74:24-75:3, 75:10-22, 75:23-24, 90:15-17, 90:3-17, 91:13-16, 91:3-10, 91:13-16, 103:7-104:10, 118:12-120:3, 118:18-22, 120:20-121:3, 122:6-10, 128:10-19, 141:6-15, 145:4-146:11, 151:25-152:7, 154:5-12, 156:13-157:14, 157:18-</p>		<p>158:4, 158:7-17, 58:18-159:8, 160:21-25, 161:8-162:12, 163:13-18, 166:9-18, 167:6-12, 167:18-20, 168:3-15, 169:24-170:2, 171:11-15</p>

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
			21, 158:8-12, 160:22-161:10, 163:19-24, 163:25-164:5, 164:9-20, 169:25-170:4, 170:11-18, 175:24-176:12, 177:5-9, 177:21-23, 186:25-187:14, 190:4-14, 195:23-196:6, 195:9-197:6, 203:12-204:15, 206:21-207:2, 210:6-15, 210:16-212:5, 218:25-219:5, 226:8-18, 233:8-12, 235:23-25, 236:18-19, 245:12-25, 245:23-25, 248:15-23, 248:20-23, 248:8-23, 251:19-24, 251:19-252:6, 258:20-259:5, 262:2-12		
	'434 Patent				
1.	dissolving the resultant oxycodone free base or oxycodone HCl from step (i) in a suitable recrystallization	plain and ordinary meaning (i.e., creating a solution of the oxycodone free base or oxycodone HCl from	'434 patent at claims 3-5, 8:12-25, 21:14-15, 25: 31-32, 26:4-5, 35: 21-25, and Examples 1, 2, 3, 5	creating a solution of the resultant oxycodone free base or oxycodone HCl from step (i) for	'434 patent at claim 1, 25:26-33, 25:37-50; 25:66-26:5, 26:1-30; 26:40-46, 27:1-12,

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
	solvent	step (i) with a solvent that is capable of recrystallization.)	Exhibits 1-3 to Plaintiffs' Preliminary Brief re '434 patent (D.I. 288-1 to D.I. 288-3).	recrystallization at or above 70 degrees Celsius using a solvent where oxycodone HCl or oxycodone free base is reasonably soluble at temperatures above room temperature and insoluble or nearly insoluble at temperatures at or below room temperature, and where the impurity is soluble at or below room temperature or insoluble at all temperatures	31:13-15, 35:2-14, 36:9-14. Exhibits 4 – 9 to Collegium's Opening Claim Construction Brief re: '434 patent (D.I. 289-4 – 289-9)
2.	cooling the recrystallization solvent to precipitate	lowering the temperature to cause purified oxycodone free base or oxycodone HCl to come out of solution	'434 patent at claim 1, 7:5-13, 8:12-13, 8:24-34 '919 patent at claims 1, 2, 16, 22 Exhibits 1-3 to Plaintiffs' Preliminary Brief re '434 patent	lowering the temperature to cause purified oxycodone free base or oxycodone HCl to come out of solution in crystalline form	'434 patent at claim 1, 25:44-50, 26:25-29, 35:2, 35:13-14 Exhibits 6 – 9 to Collegium's Opening Claim Construction Brief re: '434 patent (D.I. 289-6 – 289-9)

	Claim Term	Plaintiffs' Proposed Construction	Plaintiffs' Supporting Evidence	Defendant's Proposed Construction	Defendant's Supporting Evidence
			(D.I. 288-1 to D.I. 288-3). Exhibit A to Plaintiffs' Reply Brief re '434 patent (D.I. 293-1).		